The Effect of Navakarshaka Kashaya Ghana satwa in the Management of Ekakushta (Psoriasis): A Randomized Comparative Single Blind Clinical Trial

Y. Raghavendra*, Hiremath V. Kashavva**

Abstract

Background: It's difficult to lead the life with skin disease as it account for a great deal of misery, suffering, incapacity and economic loss. *Ekakushta* is a *vatakapha pradhana tridoshaja vyadhi* and is prime among the *Kshudra kushtas and its lakshanas* resembles with the Psoriasis. There is a need for more comprehensive, economical and safe method of management for Psoriasis. Hence the present study was conducted to evaluate the efficacy of *Navakarshaka Kashaya Ghanasatwa* in the management of *Ekakushta* (Psoriasis). **Methods:** 40 patients of *Ekakushta* fulfilling the inclusion criteria were randomly selected and divided into 2 groups, comprising 20 patients in each group. Clinical signs and symptoms were given suitable grading according to their severity along with PASI scoring. After completion of the treatment results were assessed and statistically analyzed to know the significance. **Results:** In total PAASI 48.53% improvement was seen in Group A compared to Group B with significance of 0.0004. After considering overall therapy with all the parameters 47.07% i.e moderate improvement by *Navakarshaka Kashaya Ghanasatwa* was observed.

Keywords: Navakarshaka Kashaya; Kushta; Ekakushta; Psoriasis.

Introduction

The word 'Kushta' is a broad term, which covers almost all the skin diseases. It means which despises by vitiation as well as discoloration of the skin.[1] *Ekakushta* is prime among all the *Kshudrakushta*.[3] In the present study *Ekakushta* is compared to Psoriasis due to its maximum resemblance. Psoriasis is the oldest recorded skin disease. It is a multifactorial disease of unknown origin and is universal in occurrence. The most characteristic lesions consist of erythematous, scaly, sharply demarcated, indurated plaques, present particularly over extensor surfaces and scalp.[4] Lesions vary in size from a pin point

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papule to plaque that covers larger area of the body. Its prevalence in different populations varies from 0.1%-11.8%.[5] In India, it varies from 0.84%-5.6%.[6] It is equally common in both sex.

Contemporary science treats Psoriasis with PUVA and corticosteroids. But the therapy gives serious side effects like liver & kidney failure, bone marrow depletion[7] etc. Hence it is the need of time to find out safe and effective medicine for psoriasis and here comes the role of Ayurveda. The unique treatment modality of ayurveda provides long lasting results and a better life to patients through its three basic principles of treatment i.e. – *Shamana, Shodhana*, and *Nidana parivarjana*.

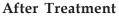
Navakarshaka[8] Kashaya is used in Kushta, Kapalakushta, Vatarakta, Pama, and Raktamandala in yogymatra. Kashaya is prepared by Triphala, Nimba, Manjistha, Vacha, Katukarohini, Guduchi and Daruharidra. Thus obtained Navakarshika kashaya is subjected to prepare Ghana by the method of Rasakriya[9] and filled to capsules of 500 mg each to evaluate the effectiveness of preparation in treating Ekakushta (Psoriasis).

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Plate 1: Before Treatment





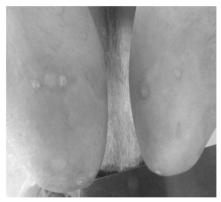


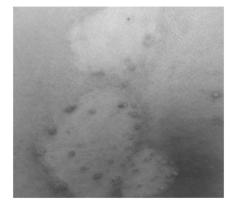
Plate 2: Before Treatment



Aims and Objectives

The aim of the present study was to evaluate the "Efficacy of *Navakarshaka Kashaya Ghanasatwa* in the management of *Ekakushta* (Psoriasis)".

After Treatment



Materials and Methods

Source of data

A. Selection of Clinical Participants

40 Patients of Ekakushta (Psoriasis) were selected from OPD and IPD of KLEU's Ayurveda hospital, Shahapur, Belgaum.

B. Drug Procurement

The raw drugs of Navakarshika Kashaya

Plate 3: Before Treatment



After Treatment



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were collected from GMP approved KLE Ayurved Pharmacy and were authentified from AYUSH approved Central Research Laboratory of KLE University Shri BMK Ayurveda Mahavidyalaya, Belagum. '777' oil[10,11] is procured from Dr. JRK's Siddha Research and Pharmaceuticals Pvt. Ltd.

Methodology

Method of Preparation of Navakarshika kashaya: (Ingredients of Navakarshaka Kashaya⁸ Table 01)- Kashaya (Decoction) was prepared using 1 part of Navakarshika kashaya (course powder) bharad (18kg) and 16 parts of water(288 lit) was added and boiled on medium flame (95-105°C) till it gets reduced to $1/4^{\text{th}}$ part (72 liters). Then kashaya (Decoction) was filtered and stored in clean vessel. Obtained Navakarshika kashaya (71.5 liter) was heated on medium flame till water portion was evaporated.[9] The residue was scraped well, collected and kept in drier at the temperature of 40°C for 2 hours every day for 15days for complete drying. Later this was powdered (2 kg) into finest form, filled in capsules (500 mg/cap) and preserved in a sterile container.

C. Method Of Collection Of Data:

- 1. *Study Design:* This is a comparative single blind clinical study with pre-test & posttest design where in 40 diagnosed Ekakushta patients of either sex were randomly assigned into two groups each comprising of 20 patients. A specially designed proforma with all points of history taking, physical signs and routine laboratory investigations were employed.
 - *a.* Group A: Patients of this group were given Navakarsha kakashaya Ghanasatwa (500mg) 2 Cap / Bid internally after food and '777' Oil for local application twice a day.
 - b. Group B: In this group patients were given Placebo (Wheat flour) 2 Cap/ Bid internally after food and'777' Oil for local application twice a day.

- Diagnostic Criteria: Based on lakshanas of Ekakushta and signs of Psoriasis -Mahavastu (Effected Area), Matsyashakhalopama (Scaling), Asweda (Rukshatwa-Dryness), Shyava – Aruna varna (Erythema), Kandu (Itching), Candle grease Sign, Auspitz Sign, Koebner phenomenon
- 3. *Inclusion Criteria:* Patients presenting with Signs and Symptoms of Ekakushta (Psoriasis), aged between16-70 years and patients of either sex
- 4. *Exclusion criteria:* Pregnant and lactating women and Psoriasis patient presenting with other systemic disorders.
- 5. Assessment Criteria:
 - 1. Grading of Signs and symptoms-Table No. 2.
 - 2. PASI score[12]
- 6. Overall Assessment of Therapy
 - *i.* Complete Remission: 100% relief in the signs & symptoms.
 - *ii. Marked Improvement:* 61%-99% relief in the signs & symptoms.
 - *iii.* Moderate improvement: 31%-60% relief in the signs & symptoms.
 - *iv. Mild Improvement:* Below 30% relief in the signs & symptoms.
- Duration and Follow Up: Duration of study was for 30 days, consists of screening and enrolment on baseline day. Follow up visits during the study period were on 7th, 14th, 21st& 28th days with window period of 2 days.
- 8. *Statistics Analysis:* For the statistical analysis, wilcoxon sign rank method, Mann Whitney method and 't' test is applied to assess the significance within the groups and between the groups.

Observations

The observations made on 40 patients showed that maximum number of patients 67.5% were in between Age group of 25 to 55

Sl no	Name of the drug	Latin Name	Part used	Proportion
1.	Amalaki	Emblicaofficinalis Linn,	Fruit	1 part
2.	Bibhitaki	Terminaliabelliri ca Roxb.	Fruit	1 part
3.	Haritaki	Terminaliachebula Retz	Fruit	1 part
4.	Nimba	Azadirachtaindica A. Juss.	Stem bark	1 part
5.	Manjishta	Rubiacordifolia Linn, Root	Root	1 part
6.	Vacha	Acorus calamus Linn,	Rhizome	1 part
7.	Katurohini	Picrorhizakurroa Royle ex Benth	Rhizome	1 part
8.	Guduchi	Tinosporacordifolia.Willd.miers	Stem	1 part
9.	Daruharidra	Berberisaristata DC.	Rhizome	1 part

Table 1: Showing Ingredients of Navakarshaka Kashaya

Sl. No	Signs and Symptoms	Observations	Score
1)	Mahaavaastu	No lesions	0
,	(Area affected)	Partial involvement of any one Part	1
	Body Parts- Hand, Leg, Neck,	Partial involvement of any 2 parts	2
	Scalp, Trunk	Lesions on most part of body	3
	1	Lesions on whole body	4
2)	Rookshatwa or Asweda	No line on scrubbing with nail	0
,	(Dryness of lesion)	Faint line on scrubbing by nails	1
		Lining & even words can be writte on	
		scrubbing by nail	2
		Excessive Rukshata leading to Kandu	3
		Rukshata leading to crack Formation	4
3)	Matsyashakalopama	No scaling	
/	(Silvery scaly lesions)	Mild scaling by itching/rubbing(from	0
		some lesions)	1
		Moderate scaling by itching/rubbin (from	
		all lesions)	2
		Severe scaling by itching/rubbing(from	
		all lesions)	3
		Scaling without rubbing/itching (from all	
		lesions)	4
4)	Shyaava –Aruna Varna	Normal skin.	0
	(Erythema)	Faint or near to normal.	1
		Blanching + red colour.	2
		No blanching + red colour.	3
		Red colour + Subcutaneous.	4
5)	Kandu (Itching)	No itching	0
,		Mild / occasional itching	1
		Moderate (tolerable) infrequent	2
		Severe itching frequently	3
		Very severe itching disturbing sleep	
		And other activities	4
6)	Candle grease sign	Absent	0
,		Improvement.	1
		Present.	2
7)	Auspitz sign	Absent.	0
,		Improvement.	1
		Present.	2

Table 2: Gradings of Lakashanas and Signs

 Table 3: Lakshanas of Ekakushta of Group A before and after the Treatment (Mann-Whitney U test)

Parameters	Mean BT	Mean AT	Mean Diff. + SD	P value	Sig	% of Change
Mahavaasthu	2.0+1.07	1.00+0.72	-1.0+ 0.64	0.0014*	Yes	50.0%#
Kandu	1.90 + 1.45	0.20+0.89	1.70 + 1.42	0.0015*	Yes	89.47%#
Asweda	3.00+1.03	0.70+1.03	2.30 + 1.17	0.0002*	Yes	76.67%#
Matsyashakalapoama	3.05+0.76	0.60+0.94	2.45 + 0.89	0.0001*	Yes	80.33%#
Shyava-aruna varna	3.25+0.85	1.45 + 0.83	1.80 + 0.95	0.0001*	Yes	55.38%#
Candle grease sign	1.50 + 0.80	0.20+0.52	1.30+0.86	0.0004*	YES	86.67%#
Auspitz sign	1.25+0.97	0.05+0.22	1.20+0.95	0.0010*	YES	96.00%#

*P<0.05, #applied Wilcoxon matched pairs test

Table 4: Lakshanas of Ekakushta of Group B before and after Treatment (Mann-WhitneyU test)

Parameters	% of Change Table 5: Perce in Group A	% of Change entage of Impro in Group B	Diff. wement	inZ-LViktslea	næsvbetæveen	the
Mahavaasthu	50 %	22.5%	27.5	2.4887	0.0146*	
Kan du	89.47%#	39.47%#	50	-1.7042	0.0499*	
Asweda	76.67%#	35.71%#	40.96	-3.0161	0.0026*	
Matsyashakalapoama	80.33%#	30.91%#	49.42	-4.0305	0.0001*	
Shyava-aruna varna	55.38%#	11.11%#	44.27	-4.0305	0.0001*	
Candle grease sign	86.67	33.33	53.37	-2.9890	0.0028*	
Auspitz sign	96.00	46.67	49.33	-2.4886	0.0128*	

*P<0.05, #applied Wilcoxon matched pairs test

*P<0.05, #applied Wilcoxon matched pairs test

religion, 40% belonged to lower middle class, Maximum number of patients i.e. 37.5% were Businessmen, 67.5% were habituated to mixed diet, 35% were addicted to Alcohol and smoking.

Maximum number of patients 42.5% was having *Vata- pitta Prakriti*. 12.5% patients reported both Anxiety (*Udvega*) and Irritation, 60% patients were suffering from disturbed sleep, 22.5% patients were taking frequently curd at night, *Dugda* with *Matsya* was taken by 7.5% patients. In this Study 50% patients belonged to *Madhyama Koshta*. family history, 45%

patients had Chronicity from 1-5 years. 60% patients had aggravation during winter season and 72.5% showed plaque type of psoriasis. 75% patients had the involvement of more than one parts of body. 12.5% patients had the lesions only on the scalp.

Results

In group A highly significant improvement was there in *Matsyashakalopama* (Scaling) and

Parameters	Mean BT	Mean AT	Mean Diff. + SD	P value	Sig	% of Change
Head	0.50 <u>+</u> 0.57	0.15 <u>+</u> 0.23	0.35 <u>+</u> 0.46	0.0028*	Yes	70.00%#
Upper limbs	1.29 <u>+</u> 1.29	0.69 <u>+</u> 0.65	0.70 <u>+</u> 0.77	0.0007*	Yes	53.88%#
Lower limbs	3.51 <u>+</u> 3.33	1.52 <u>+</u> 2.06	1.99 <u>+</u> 2.07	0.0004*	Yes	56.70%#
Trunk	2.65 <u>+</u> 2.75	1.11 <u>+</u> 1.55	1.54 <u>+</u> 1.65	0.0005*	Yes	58.11%#
Total	7.95+6.27	3.36+3.99	4.60+3.91	0.0001*	Yes	57.80%#
		*D<0.0E	Hannalia Janaina Jakasat			

Table 6: PASI Scores of Group A before and after treatment (Unpaired t Test)

*P<0.05, #applied paired t test

Table 7: PASI Scores of Group B before and after Treatment (Unpaired t Test)

Parameters	Mean BT	Mean AT	Mean Diff. + SD	P value	Sig	% of Change
Head	0.52 <u>+</u> 0.50	0.47 <u>+</u> 0.58	0.05 <u>+</u> 0.28	0.4283	No	9.71%#
Upper limbs	1.33 <u>+</u> 1.37	1.19 <u>+</u> 1.32	0.14 <u>+</u> 0.32	0.0641	No	10.53%#
Lower limbs	4.30 <u>+3</u> .83	3.78 <u>+</u> 3.54	0.52 <u>+</u> 0.98	0.0284*	Yes	12.09%#
Trunk	2.76 <u>+</u> 3.31	2.63 <u>+</u> 3.40	0.13 <u>+</u> 0.82	0.4890	No	4.72%#
Total	8.90+7.93	8.08+7.72	0.83+1.78	0.0522	No	9.27%#

*P<0.05, #applied paired t test

Shyava-aruna varna (Erythema) with 80.33% (P=0.0001) and 55.38% (P=0.0001) respectively. Other symptoms shown significant results with 89.47% (P=0.0015) reduction in Kandu (itching), 76.67% (P= 0.0002) in Aswedana (Dryness), and 50%(P=0.0014) of improvement was there in Mahavasthu (Area of Lesions). 86.67% improvement was assessed in the Candle grease sign with significance of 0.0004 and 96.00% in Auspitz sign (P=0.0010). In Total PAASI Score highly significant improvement of 57.80% (P=0.0001) reduction was observed. Good improvement of 70% (P=0.0028) was there in the head compared to other part of body. 53.88% (P=0.0007) reduction of PAASI score in upper limb, 56.70% (P=0.0004) in the lower limbs and 58.11% (P=0.0005) improvement observed in the Trunk region (Table 3).

In Group B Significant improvement of 35.71% (P=0.0038) in *Asweda* (*Rookshata*) and

Matsyashakalopam(scaling) was reduced by 30.91% (P=0.0047). No significant changes were observed in other *Lakshanas*. In signs 33.33% of improvement was seen with significance of 0.0330 in Candle grease sign, and with no significance 46.67% (P=0.1095) improvement in Auspitz sign was observed. Total PAASI and other part of the body PAASI do not shown any significant results (Table 4).

After comparing the percentage of improvement between the groups in Signs and symptoms, highly significant improvement observed in *Matsyashakalapoama* (Scaling) and *Shyavaaruna varna* i.e with difference of 50% (P=0.0001) and 44.27% (P=0.0001) respectively in group A compared to Group B. Significant improvement observed in other symptoms i.e 40.96% (P=0.0026) in *Rookshata*, 50% (P=0.0499) in *Kandu* and 27.5% (P=0.0146) in *Mahavasthu*. Group A shown 53.37% (0.0028) in Candle grease sign and 49.33% (P=0.0128)

Table 8: Percentage of Improvement between the Groups A and B in PAASI (AppliedPaired t Test)

Parameters	% of Change	% of Change	Diff. in	t-	Р-
rarameters	in Group A	in Group B	⁰∕₀	Value	value
Head	70.00	9.71	60.29	2.5166	0.0162*
UpperLimbs	53.88	10.53	43.35	2.9826	0.0050*
Lower Limbs	56.70	12.09	44.61	2.8668	0.0067*
Trunk	58.11	4.72	53.39	3.4195	0.0015*
Total	57.80	9.27	48.53	3.9213	0.0004*

in the Auspitz sign more compared to Group B (Table 5).

Comparing both the Groups in PAASI Score, Group A has shown significantly more improvement than group B with 60.29% (P=0.0162) in scalp psoriasis, 43.35% (P=0.0050)in upper limbs, 44.61% (P=0.0067) in Lower limbs and in Trunk 53.39% (P=0.0015). Where in Total PAASI 48.53% improvement was seen in Group A compared to Group B with significance of 0.0004. (Table 8)

Discussion

1. Mahavastu

Stress, Season and Autoimmnity are the precipitating factors which exacerbates the existing disease condition leading to the further extension of the lesions[13] which can be understood as *mahavastu*. Stress results in the tissue injury by increasing the oxidative stress in the tissues. It can be inferred that increased Autoimmunity results in the increased activation of CD4 cells and CD8 cells which leads to the destruction of tissues by their phagocytosis.[14]

In present study, Navakarshaka kashaya Ghanasatwa retarded further expression of the lesions, which may be due to the Antioxidant and immunomodulatory activity of the drugs like *Triphala*, *Manjista*, *Daruharidra*.

Manjista and Daruharidra with their Rakthashodaka property along with Ushna virya of other drugs might have reduced the tendency of spreading by 27.5%.

2. Matsya Shakalopama (Scaling)

Studies have shown that autoimmunity when affect the dermatomes results in the excessive production of immature keratocytes with a reduced span results in hyper proliferation leading to scaling.[15] Present study showed significant reduction of scaling by 49.42% which may be due to synergistic effect of the formulation, which exhibited through immune modulatory action of *Guduchi, Manjishta, Daruharidra.*

Further *Guduchi manjista* etc. drugs are known for their leucocytosis action which results in suppression of the leucocytes i.e. Monocytes which are responsible for the suppression of IL-6 and IL-8. Hence suppression of Leucocytes might have lead to Suppression of Interleukin production resulting into reduction of scaling.

3. Shyava-aruna Varna

Researches showed that, in psoriasis inflammatory mediators like IL-17 and TNF cytokines disrupt the pigment production of melanocytes. Increased local blood circulation during inflammatory period exerts erythema of the skin.[16] *Triphala, Guduchi* are known for their anti-inflammatory action and might have corrected the impaired melanin production by 44.27%.

4. Kandu

Local inflammatory mechanisms may induce pruritis in many dermatoses along with various inflammatory mediators (Neuropeptides), which are released as a result of inflammation from dermal nerve endings which results in Pruritis.[17] Neuropeptides, Mastocytes, Dendriticcells, Lymphocytes, Macrophages and Neutrophils will produce vascular changes in the skin by inducing angiogenesis, dilatation of vessels.[18]

Ingredients of the formulations like *Guduchi*, *triphala*, *manjista*, *daruharidra* have antiinflamatory properties by virtue of which it might have act over nueropeptides to reduce the itching by 50%.

5. Rookshata

It is known that abnormalities of sweat gland function in the Psoriasis leads to lack of sweat in the lesion and causes the dryness.[19] In the diseases like Dry eczema and Psoriasis - dry, rough skin and lack of sweating is seen due to slow oxidation.[18] Antioxidant activity of Triphala, *Manjista* and *Daruharidra* might have helped to reduce the *Rukshta* (Dryness). Rukshata is main property of *Vata dosha*. Except Amalaki and *Nimba* other constituents of Navakarshaka kashaya are having *Ushana* virya which acts as *Vatahara*, this might have reduced *rukshata* 40.96% in the present study.

Most of the drugs of Navakarshaka kashaya with *Tiktha Rasa* and *Katu Vipaka* does *agni dipana, Amapachan* and *Raktha shodana. Tiktha rasa* and *kashaya rasa* are known for there *kapha shoshana,* Kleda shoshana, Kanduhara, *Ropana, Twak mamsa sthirikarana karma,* thus desorption of excessive *Kapha* dosha which may be present in the form of *Kleda* in *Shareera.* Hence this *Kapha rukshana* leads to *shroto shodana.* Further *Gunas* lika *Laghava, Vaishadya* also does *Kapha shoshana. Ushna* rectifies *Anuloma gati* of *Vayu* which act as *Vatahara.*

Hence correction of *Ama*, enhancement of *Jataragni* and *Dhatwagni*, restoration of normal functions of *Vata* might have suppressed the *Ekakushta Lakshanas* as the definition of *Kushta* says- Pathalogy Manifesting inside in the *koshta* and exhibiting its *lakshana* in the *Twak*.

Conclusion

132

Present study with two groups one with trail drug Navakarshaka Kashaya Ghanasatwa and other with Placibo, but both groups has the same local application. With proper statistical application considering overall therapy, it was found that Navakarshaka Kashaya Ghanasatwa is having 47.07% efficacy in the management of *Ekakushta* (Psoriasis), i.e in total proves to be having moderate efficacy in treating the disease *Ekakushta* (Psoriasis).

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